

INTERNET COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference JE/P/193/WOD	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/02364	International filing date (day/month/year) 29.05.2003	Priority date (day/month/year) 31.05.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/02		
Applicant PSIMEDICA LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10.12.2003	Date of completion of this report 17.08.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Muñoz, M Telephone No. +31 70 340-4542



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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-17 as originally filed

Claims, Numbers

1-28 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 25-28

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 25-28 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-21,23
	No: Claims	22,24
Inventive step (IS)	Yes: Claims	1-21
	No: Claims	22-24
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

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Re Item III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 25-27 are broader than justified by the description.

The description consistently refers to the making of orthopaedic scaffolds based on bioactive silicon obtainable via self-assembly of blocks. No other application is mentioned or even envisaged in the application.

In turn, claim 27 relates to the building of any object via the self-assembly of blocks made of any material. Claims 25-26 relate to the building of any object via self-assembly of blocks made of a material comprising silicon.

Clearly those claims are broader than justified by the description and in this sense claims 25-27 are not considered as fully supported by the description as required by Article 6 PCT.

Under Rule 6.2(a) PCT, claims should not rely on references to the description. Claim 28 does not meet this requirement. Therefore claim 28 does not meet the requirements of clarity set forth in Article 6 PCT, when taken in combination with Rule 6.2(a) PCT.

Following Article 34(4)(a)(ii) PCT, this International Preliminary Examining Authority, using its discretion, has decided not to formulate an opinion with regard to novelty, inventive step and industrial applicability on the subject-matter of claims 25-28.

Re Item V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO 01/95952 (2001-12-20)

1. D1 relates to silicon or silicon composites (with polymers) orthopaedic implants. Figure 1h and the related description found on page 23, line 26 to page 24, line 16 clearly describes an orthopaedic scaffold based on the assembly of multiple building elements via covalent bonding or biocompatible adhesives. When assessing novelty the broadest definition of terms used in the claims shall be used. The terminology block used in claim 22 is understood as covering structural units of an assembly without restriction of shape or form. As a results the elements used in D1 (pieces of wafers) when used in the construction defined in D1 are considered as falling under the definition of blocks.

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Therefore, the content of D1 anticipates the subject-matter of claims 22,24 (Article 33(1) and (2) PCT).

2. The subject-matter of claim 1 differs from that of D1 in that the blocks are treated in a way that self-assembly of two or more blocks is possible.

The subject-matter of claims 1-21 is therefore novel (Article 33(1) and (2) PCT).

3. D1, which is considered as the most relevant state of the art, relates to the problem underlying the application, that is the provision of silicon based orthopaedic scaffolds.

The difference between the teaching of D1 and the subject-matter of claim 1 relies on the provision of a different process of making multi-block silicon orthopaedic scaffolds by treating at least one the surface of said blocks such that it will adhere to a similarly treated block-surface via self-assembly.

The problem to be solved may therefore be considered as the provision of an alternative process for preparing orthopaedic scaffolds.

The solution proposed by the applicant consisting in using self-assembly process is neither disclosed nor fairly suggested in the prior art at hand. It is additionally not an obvious modification from the process disclosed in the prior art.

Therefore it is considered that the subject-matter of claims 1-21 involves an inventive contribution under Article 33(1) and (3) PCT.

4. The difference between the subject-matter of claim 23 and the teaching of D1 relies on the selection of a composite comprising silicon rather than the bioactive silicon of D1. Such a slight difference cannot be considered to bring an inventive contribution to the claim. It is to be noted that although the self-assembly feature appears, from the reading of the description and after evaluation of the prior art at hand, to be the general inventive idea underlying the application, this feature is absent from claim 23.